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Attachment D: 510(k) SUMMARY of Safety and Effectiveness

Submitted by: Rob Butler (contact person), Regulatory Approvals
Hewlett-Packard Company - Medical Products Group
3000 Minuteman Road
Andover, MA 01810
phone (508) 659-2785; fax (508) 687-8284
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Device Trade Name: HP 77010CF Ultrasound Imaging System
Device Common Name: HP SONOS 100CF Ultrasound Imaging System
Classification Name: FDA has classified Ultrasound Imaging Systems as Class II in 21 CFR:

870.2100 Cardiovascular Blood Flowmeter
870.2120 Extravascular Blood Flow Probe
870.2330 Echocardiograph
870.2880 Ultrasonic Transducer
870.2890 Vessel Occlusion Transducer
882.1240 Echoencephalograph
884.2225 Obstetric-gynecologic Ultrasonic Imager
884.2960 Obstetric Ultrasonic Transducer and Accessories
892.1550 Ultrasonic Pulsed Doppler Imaging System
892.1560 Ultrasonic Pulsed Echo Imaging System
892.1570 Diagnostic Ultrasonic Transducer

Predicate Devices: In this 510(k) submission, the legally marketed devices to which we claim equivalence are the HP/Philips P800 Ultrasound Imaging System (K935923) and the Sharplan Usight 9010 Laparoscopic Ultrasound System (K945796).

Device Description: This 510(k) submission is to add an endovaginal transducer and a new EV(EndoVaginal)/Pelvic study type to the HP SONOS 100CF Ultrasound Imaging System.

Intended Use: This modification expands the intended use statement for the HP SONOS 100CF Ultrasound Imaging System to include obstetrics and gynecology applications.

Technological Characteristics: This modification includes an OEM endovaginal transducer which is identical to the endovaginal transducer used with the Sharplan Usight 9010 Laparoscopic Ultrasound System. All other technological characteristics of the modification are consistent with the currently marketed (unmodified) HP SONOS 100CF Ultrasound Imaging System.

The safety of this modification is shown by compliance to medical device safety standards (such as IEC 601 and UL 544) and by the acoustic output data provided in this submission. Software safety is verified by hazard analysis and software validation to ensure performance specifications are met. This validation, safety testing, acoustic output testing, and comparison to legally marketed devices demonstrate that this modification is substantially equivalent to the legally marketed predicate devices with regards to safety, effectiveness and intended use.